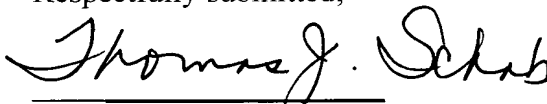
 a removable tightening rod disposed within said tubular rod for sealing said open bottom end of said rod from communication with the atmosphere after said liquid component is introduced into said mixing vessel, said tightening rod initially disposed within said tubular rod prior to introduction of said components into said mixing vessel, and adapted for removal from said tubular rod immediately prior to introducing said components into said mixing vessel, and reinsertion immediately after said components are introduced, wherein said powder and liquid components are introduced into said vessel interior and mixed therein under a continuous vacuum from said vacuum source while atmospheric air is prevented from entering into said vessel due to said tightening rod, whereby harmful component emissions resulting from mixing are prevented from escaping said vessel.--

REMARKS

This preliminary amendment is in response and according to Examiner Sohoo's comments of his June 23, 1997 Office Action. The claims of the "clean" specification reflect what claims are considered pending. The new claims listed above are to be added; they were numbered with the next highest number from the last claim number of the previous file.

Respectfully submitted,



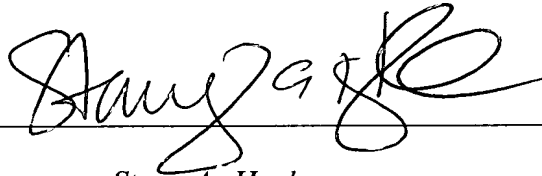
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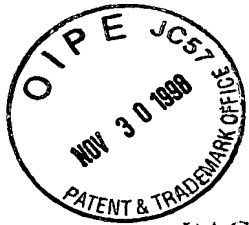
JONSSON, Sören
C-35890
November 23, 1998
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D. C. 20231, on November 23, 1998.

A handwritten signature in black ink, appearing to read "Stacy A. Hagle", is written over a horizontal line.

Stacy A. Hagle



[ARRANGEMENT]

METHOD AND DEVICE FOR FEEDING COMPONENTS FOR
BONE CEMENT INTO A MIXING VESSEL FOR THESE [INTENDED FOR
THEM]

BACKGROUND OF THE INVENTION

1. Field of the Invention

5 The present invention relates to a method for successively feeding batches of constituent components into a mixing vessel for the preparation of bone cement under vacuum. The invention also relates to an ^{ARRANGEMENT} [apparatus] for successively feeding batches of constituent components into a mixing vessel under partial vacuum for the preparation of bone cement.

10 2. Description of the Prior Art

Bone cement is prepared by mixing polymethyl methacrylate in ^[10] powder form

[AND] with liquid monomethylmethacrylate in a mixing container. Both the liquid component and the combined mixture give off substances in gaseous form which are environmentally harmful and injurious to human health. For this reason, it is important ^{both} for the introduction of the bone cement components into the mixing container and the mixing process itself, to take place in such a way that the smallest possible quantity of the harmful gases escape into the surrounding environment. Mixing vessels have been developed where the ^{[by means of which both the introduction of the} introduced components ^{and the preparation of]} were successfully prepared into bone cement ^[can be prepared] without a substantial ^[the] release of the aforementioned gases. However, in order for the bone cement to develop its optimal strength during use, it is also important for the components ^[contained in] comprising the cement to have well-mixed, predetermined proportions.

[to a significant degree are described in SE-C-8901599-4 and SE-AO-9201353-1, for example]



SUMMARY OF THE INVENTION

The object of the present invention is to make available a method and device ^[by way of introduction] of the kind described above, which avoids the risk of gas release when feeding the bone

cement components into the mixing vessel. This is achieved in accordance with the

5 that according to the method and in an arbitrary sequence invention in a number of ways. According to one method, a glass ampoule containing a [bone cement]

liquid component of a bone cement is surrounded by a container which is in reclosable

communication with the atmosphere. ^[and with] A second container surrounds the first container so

that when the mixing vessel is opened, ^[so that] the contents of the ampoule, under the effect of a

partial vacuum inside the mixing vessel, can be sucked down into it, in that a space [formed

10 between the aforementioned inner container and outer container] ^[by the] ^[that encloses it at least partially and] is filled with a second

bone cement component in powder form which is caused by displacement of the inner

container relative to the outer container, to move from a first position in which the space

does not communicate with the atmosphere or the mixing vessel, then to a second position

in which the space ^[it] communicates with the atmosphere and the mixing vessel, so that the

15 powdered bone cement component ^[in powder form can be] is sucked down into the mixing vessel under the effect

of the partial vacuum inside it.

[An arrangement]

A device for carrying out the above method in accordance with the invention

is characterized in that it comprises ^[on the one hand] an inner container communicating with the

atmosphere, ^[which] and ^[a] is so arranged as to enclose the glass ampoule containing the liquid bone

20 cement component, and to communicate with the aforementioned mixing vessel, and which

includes ^[comprising] means for opening the ampoule so that its contents, under the effect of the partial

vacuum inside the mixing vessel, can be sucked ^[down] into it. ^[and on the other hand an] The outer container at least

partially encloses ^[enclosing] the inner container ^[at least partially] and is also arranged ^[so] so as to communicate with the

mixing vessel ^[the atmosphere, which outer container] and together with the inner container, defines a space therebetween which

25 is filled with a certain quantity of ^[a] ^[component in powdered form and in which] the powdered component of the bone cement. The inner

container is capable of displacement ^[between] from a first position to a second position, the first

position characterized by the inner container preventing ^[in which sections of] ^[prevent] communication between both the

mixing vessel and the atmosphere, and ^[to a] the second position characterized, in which

communication between the mixing vessel on the one hand ^[and] the the atmosphere on the other

30 hand is open, so that the bone cement component in powder form, under the effect of the

partial vacuum inside the mixing vessel, can be sucked ^[down] into it without escape of gases.

[Especially advantageous forms of the arrangement in accordance with the invention can be appreciated from the following description.]

According to another method, which has a couple of variants, the outer or second container is eliminated and the mixing vessel is prefilled with the powder bone cement component. The first container holding the ampoule of the liquid bone cement component connects to the mixing vessel in a manner where displacement of a container cap causes the liquid component to be sucked into the mixing vessel under vacuum.

According to yet another method, the first and second containers are eliminated and the liquid bone cement component is supplied through a collapsible plastic bag and tubing arrangement attached thereto. The tubing can be connected to the mixing vessel in at least two convenient locations, where a tubing clamp is released to allow the liquid component to flow into the mixing vessel under pressure.

Along the same lines of eliminating the first and second containers, another method of the present invention simply involves providing a glass ampoule with the liquid component therein, breaking the ampoule, and then supplying the contents into the mixing vessel through a funnel attached thereto. Again the liquid component is sucked under vacuum into the mixing vessel.

A final method of the present invention again involves use of a first container for holding an ampoule, but now the container is melded to the mixing tube for directly draining into the bottom of the mixing vessel.

The devices for carrying out all methods in accordance with this invention are more fully detailed in the following sections.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described below in greater detail with reference to the accompanying drawings, in which: [illustrates schematically]

Figure 1 is a cross-sectional view in longitudinal section of an embodiment of a feeding/mixing device of the present invention with the mixing vessel filled with bone cement components in liquid and powder form, [especially, and attached to a mixing vessel.]

Figure 2 illustrates the feeding of the liquid bone cement component into the mixing vessel, [and]

Figure 3 illustrates the feeding of the powder bone cement component into the mixing vessel; [.]

Figure 4 illustrates a second embodiment of the invention in accordance with

longitudinal cross-section; []

Figure 5 illustrates feeding the liquid bone cement component into the mixing vessel of Figure 4;

Figure 6 illustrates a third embodiment of the present invention where feeding the powder component into the mixing vessel differs slightly from that of Figure 4;

Figure 7 illustrates the mixing vessel of a fourth embodiment of the present invention in which the powder form of the bone cement pre-exists within the mixing vessel;

Figure 8 illustrates a container and a cassette that houses a glass ampoule which contains the liquid form of the bone cement;

Figure 9 illustrates a cross-sectional view of the mixing vessel of Figure 7 prior to mixing the cement components;

Figure 10 illustrates the mixing vessel of Figure 9, feeding the liquid into the vessel;

Figure 11 illustrates the mixing vessel of Figure 7 with the bone cement components thoroughly mixed;

Figure 12 illustrates the mixing vessel of a fifth embodiment of the present invention in which the liquid form of the bone cement is fed into the mixing vessel through the side wall;

Figure 13 illustrates the mixing vessel of a sixth embodiment of the present invention where the liquid bone cement component is contained in a collapsible plastic bag;

Figure 14 illustrates a seventh embodiment of the present invention, which is a variant to the Figure 13 embodiment;

Figure 15 illustrates the mixing vessel of a eighth embodiment of the present invention where the liquid form of the bone cement component is contained in a separate container and fed through a funnel to admix with the powder form of the bone cement component;

Figure 16 illustrates the mixing vessel of a ninth embodiment of the present invention where the liquid cement container is inserted inside the tubular rod and joined thereto and the bone cement components are mixed by using the container as a handle for

pulling and pushing the agitator inside the mixing chamber.

Figure 16A illustrates the embodiment of Fig. 16 with a plug of the cap removed to allow air infiltration during mixing.

Figure 17 illustrates a detailed view of the connecting area between the container and the tubular agitation rod.

DETAILED DESCRIPTION OF THE INVENTION

The designations 1 and 2 are used generally in the drawings^[drawing] in respect of a feed arrangement and a mixing vessel. The latter^[former] comprises an interior 2a, a cylindrical container 3 comprised of an outer cylinder wall 3a, a bottom 4 at one end of the container and a spout 5 with a sealed opening at the other end, together with an agitator 6, received^[neck] within said spout and mixing vessel and capable of axial, vertical movement inside^[in] the container 3. The agitator 6 consists^[consisting] of an agitator disc 6a^[disc] attached to a tubular agitator rod 6b. The agitator 6^[this] is mounted so that it is free to vertically slide up and down while maintaining^[and producing] a seal in the spout^[neck] 5, in such a way that the plurality of holes 6h in agitator disk 6a can be used to bring about through mixing of the bone cement components within mixing vessel 2^[Once mixing is complete, and once a lock 7 has been removed, the bottom 4 can be axially displaced inside the cylinder by upward movement of piston head 80, moving towards the spout 5. The piston-like function of bottom 4, upwardly pushes and then discharges the mixed bone cement via the hollow agitator rod 6b, which now serves as a discharge nozzle. The interior of the container 2 communicates via a filter 8 with a vacuum source (not shown) during feeding and mixing of the bone cement components. Rapid and effective feeding of the bone cement components into the mixing vessel, and safe handling of the gases that are environmentally harmful and injurious to human health, are achieved in this way.] has been removed. the bottom 4 can be axially displaced inside the cylinder by upward movement of piston head 80, moving towards the spout 5. The piston-like function of bottom 4, upwardly pushes and then discharges the mixed bone cement via the hollow agitator rod 6b, which now serves as a discharge nozzle. The interior of the container 2 communicates via a filter 8 with a vacuum source (not shown) during feeding and mixing of the bone cement components. Rapid and effective feeding of the bone cement components into the mixing vessel, and safe handling of the gases that are environmentally harmful and injurious to human health, are achieved in this way.

The feeding of the bone cement components from the feed arrangement 1 into the mixing vessel 2 takes place via the agitator rod 6b, and the details concerning the component mixing within vessel 2 will be described later.^[on a way which]

The feed arrangement 1 of the first embodiment, shown in Figures 1-3, comprises an inner, essentially cylindrical container 9 communicating with the atmosphere and an outer, similar^[similarly essentially] cylindrical container 10^[enclosing] which at least partially^[at least partially] encloses the inner container. The container interior 9e is so arranged so as to enclose a glass ampoule 11

[C-3]
containing the liquid bone cement component A, and to communicate with the mixing vessel 2, via its agitator rod 6b, as already mentioned. The container 9 is integrally formed having a cylindrical collar 12 about its bottom end 9b with a threadable cap 18, capable of axial displacement relative to it. Removal of cap 18 allows insertion of ampoule 11 within interior 9e. [For the purpose of breaking the ampoule 11, the container 9 has a

5 In the embodiment illustrated in Figure 1, the facility for displacement to take place between the cylindrical collar 12 and the cap 18 is achieved by means of the internal collar threads 12a engaging the external cap threads 18a. The cap 18 has an opening 18d communicating between the interior 9e of the container 9 and the atmosphere, and the container 9 has a funnel-shaped top end 9a, with the narrow neck portion 9c having an outside diameter which frictionally inserts within, and discharges into the open

[Name the] agitator rod 6b. In the first embodiment in accordance with Figures 1-3, a tip 11a of the glass ampoule 11 points downwards, and there is present inside the interior 9e of container 9, a glass ampoule breaking means 13 in the form of an oblique plane 13a. Tip 11a of the glass ampoule 11, which has a fractural impression therein, rests against means 13. The bottom 18b of the cap has an annular raised wall 18w, which contacts ampoule 11, thereby clamping it between means 13 and cap 18. When cap 18 is screwed axially downwards, the tip 11a is eventually broken off against the oblique plane 13a, and the contents of the ampoule are sucked downwardly through opening 13c of means 13, into the mixing vessel

20 2 by the partial vacuum existing inside of it, as illustrated in Figure 2. A filter 14 is provided for the purpose of preventing glass splinters from the glass ampoule 11 accompanying the contents into the mixing vessel 2. In the second and third embodiment in accordance with Figures 4-6, the tip 11a of the glass ampoule points upwards, and the inner container 9 has a glass breaking means 13 in the form of an upward-facing and pointed cone 13b, against which the bottom 11b of the glass ampoule rests. The bottom

25 [12] 18b of the cap 18 is formed with vertically taller walls 18w, such that they contact ampoule 11, thereby clamping it in place. When cap 18 is screwed downwards, the bottom 11b of the glass ampoule 11 is penetrated by the cone 13b and, as previously described for the first embodiment, the contents of the glass ampoule are sucked downwardly through openings 13c, then into the mixing vessel 2. A filter 14 can also be provided. As the liquid bone cement component of the glass ampoule 11 flows down into the mixing vessel 2, air is sucked in via the opening 18d thereby sealing and preventing

[Finding their way]

the gases from the liquid bone cement component from escaping into the atmosphere.

The outer container 10 is ^{essentially identical} generally similar in shape to the inner container 9, with container 9 being concentrically arranged within at least a part of container 10.

Outer container 10 also has a top end formed as a funnel-shaped part 10a, with a reduced neck member 10c that has an ^{and} inside ^[6] diameter slightly larger than the outside diameter neck 9c of inner container 9 ^{[5] a space 15 for the bone cement component in powder form} so that neck 9c is also frictionally contacting neck member 10c.

The neck 10c has a flared end 10d which inserts over the open end of agitator rod 6b. A space 15 exists between containers 9 and 10, and the powder component B of the bone cement is to be received therebetween prior to mixing. The bottom 10b of container 10

has an outer surface 10e that is formed ^{between the} with threads 10t. Threads 10t are in threaded engagement with the internal threads 16d on downwardly depending edge 16c of interlocking cap 16, thereby closing the top of container 10. The central throughbore 16e

includes threads 16f for threadingly receiving inner container bottom collar 12. In this way, when inner container 9 is ^[in] threaded ^{engagement with the inner container 9, so that the} downwardly by engaging threads 12t against

throughbore threads 16f, grooved annular flange 12d is seated against annular seat 16h.

At the same time, O-ring 17 creates a seal against the annular upstanding lip 16g. When in this first position, the outer container is sealed at its bottom end from the atmosphere.

When inner container 9 is axially displaced within the interlocking cover 16, in an opposite direction, this seal is broken. Comparing Figures 2 and 3, it is seen that the inner container is now upwardly displaced in the axial direction wherein, the funnel-shaped tops

9a and 10a disengage each other and the containers no longer form a closure of the space ^[to a position shown in Figure 3 in which] 15 at the necks 9c and 10c. The inner container is raised until the threads 12t are run-out,

so that container 9 now allows the space 15 ^[communicates] to communicate with the inside 2a of the mixing vessel. In the latter position, channels 16j are now opened in communication with

the atmosphere ^[for the purpose of] facilitating the introduction of the powder component of the bone cement ^[component in powder form achieved] out of space 15 and into vessel 2, through the partial vacuum inside the mixing vessel.

Air allowed into container 10 ^[and for preventing the] prevents the aforementioned gases from finding their way into the atmosphere. ^[An annular seal 17 provides sealing in the first mentioned position between the upper container 9 and the bottom 10b of the outer container 10.]

The ^{differs from the} third embodiment in accordance with Figure 6, shows that the only difference between this embodiment and the embodiments of Figures 4 and 5 ^[4-5 through] is found in the brush-shaped devices 9d ^[9d's] which are arranged as to make contact with the surface of the funnel-shaped part 10a in the first position of container 9. The bone cement component

B is released from the aforementioned surface by relative ^[Emotion] rotation between the outer and inner ^[Container] containers such that trushes 10d, under weight of the powder, collapse and allow powder to fall into tube 6b.

5 A feed procedure of the above-described embodiments will ^[is] now be summarized below with reference to ^[the] Figures 1-6 of the ^[in] drawings. It should be understood that with these embodiments, ^[in accordance with the invention] the feed arrangement is supplied ready for use, ^[i.e.] meaning it is filled with the bone cement components in the correct proportions.

10 As Figure 1 illustrates, in order to permit feeding of the bone cement components into the mixing vessel 2 from the feed arrangement 1 in accordance with the invention, the mixing vessel 2 is required to be connected to an active vacuum source.

The pin ^[12c] 18c is first removed, and the displaceable ^[bottom 12b] cap 18 is screwed downwards, ^[in conjunction with which] wherein the glass ampoule 11 is also caused to move downwards. Screwing continues until the tip 11a of the glass ampoule 11 is broken off against the ^[oblique] breaking plane ^[13] 13a (See Figure 2), or until the bottom 11b of the glass ampoule is penetrated by the tip of the cone

15 ^[12a] 13b (See Figure 5). The liquid bone cement component now flows down into the mixing chamber 2 under the effect of the partial vacuum existing inside of it. Once the glass ampoule 11 is totally empty, the cylindrical ^[part 12a] collar 12 is rotated from the first and sealed position so that the inner container 9 is axially displaced upwards to the second position ^[shown in Figure 3] shown in ^[Figure 1 and 2] Figure 3, in which the space 15, which was previously closed at its top and

20 sealed from the atmosphere at its bottom, ^[to the position shown in Figure 3, in which the aforementioned space is of both at top and bottom] is now opened at the bottom, via the channels 16j, and at the neck 9c, 10c. The powder component B of the bone cement is now allowed to drop downwardly into mixing chamber 2. Once the space 15 has been completely emptied, the entire feed arrangement 1 is removed, and the inner tubular part 6b of the agitator rod 6 is sealed with a sealing rod 19 (shown in Figure 12) which seals ^[against the mouth of 6a] the bottom second end 6e. The mixing procedure can now start.

25 The feed arrangement ^[in accordance with the invention] of the embodiments just described can be modified in many ways within the scope of the invention. This is true, for example, of the facility for axial displacement between the inner container 9 and its ^[bottom 12b] cap 18, and between the inner container 9 and the outer container 10, which facility for axial displacement can be achieved other than by threaded engagement. Also, means other than the oblique plane ^[13a and 13b] 13a or the pointed cone ^[13a] 13b can be considered for the purpose of ^[opening] breaking open the ampoule 11. ^[take place] Furthermore, the emptying sequence can also occur in the reverse order to

*Component in
powder form*

that described above, i.e. first the powdered component of the bone cement can be
dropped, and then the liquid bone cement component.

Turning attention now to Figures 7-12, a fourth and a fifth embodiment of
the present invention will now be described. These two embodiments differ from the
previously described ones from the perspective that the powdered component of bone
cement pre-exists within the mixing vessel 2 prior to any mixing procedures, and that the
container 9 contains only the liquid component. It will become clearer after reading the
following description that the main characteristic of the fourth embodiment is that only the
liquid component will be drawn into the mixing vessel under vacuum like the previous
embodiments, and that a slightly different ampoule arrangement is provided wherein the
contents feed downward through the tubular agitator rod 6b, and enter vessel 2 in the
vicinity of the vessel bottom 4. The fifth embodiment uses a similar ampoule
arrangement. However, the ampoule does not rest on the mixing vessel and the contents
enter through the outer cylindrical wall 3a, also near the mixing chamber bottom 4. The
fourth and fifth embodiments, as well as the sixth one described later, are also provided
with a second filter 21, located at the top of mixing vessel 2.

In accordance with the fourth embodiment, Figures 7-11 show mixing vessel
2 as being pre-filled with the powder component of the bone cement. A tightening rod 19
is received within tubular agitator rod 6b of agitator 6 and has plug 19a and O-ring 19c
inserted within a groove 19b thereof, to form an air-tight seal so that powdered contents
B are not contacted by and affected by atmospheric air which is capable of downwardly
travelling along tubular rod 6b to vessel bottom 4. Just prior to introducing glass ampoule
11 on top of mixing vessel 2, tightening rod 19 is completely removed from tube 6b,
wherein the cylindrical container 9 is placed on top of vessel 2 by inserting funnel-shaped
neck 9c into mouth 6c at the first end 6d of tubular rod 6b. Although Figures 1-6 show
funnel-shaped top end 9a as having a slightly different contour from that of the same
section shown in Figures 7-12, it should be understood that either contour can be used
interchangeably in these embodiments. Figure 8 shows in greater detail that glass ampoule
tip 11a is pointing upwards when inserted within container 9, and that the ampoule is
resting upon the upward cone 13b of breaking means 13, said means having internal
passages 13c for allowing liquid therethrough once it passes filter 14. Figure 8 also
illustrates that cap 18 is constructed slightly modified in that cap 18 has gripping means

18h for facilitating the operative threading movement of cap 18 along container threads 12a. Figure 9 shows the ampoule 11 just prior to being broken. Figure 10 shows that when handle 18h of the cap is turned so as to downwardly displace the cap 18 through action of the interacting threads 12a and 18a, shoulder 18s pushes downwardly against ampoule 11, causing upward-facing, pointed cone 13b to break bottom 11b of the ampoule, thereby allowing liquid contents A to flow through filter 14 under suction downwardly into hollow tube 6b as previously described. As Figure 10 shows, openings 18d and 18e in cap 18, allow atmospheric air to be communicated into the interior of container 9 under suction, also as previously described, thereby preventing noxious fumes escaping to atmosphere. A small gap 23 exists between vessel bottom 4 and agitator disk 6a so that as liquid A descends tubular rod 6b, exists open end 6e, then it enters gap 23, which behaves as a passage for percolating an air/liquid mixture upwardly through holes 61h in the agitator disk 6a, so that air bubbles cause liquid A to thoroughly mix with the powder component B, while under the continuing action of the vacuum source. Figure 11 illustrates that once ampoule 11 is empty, container 9 is removed and replaced with tightening rod 19. While still under vacuum, tubular rod 6b is grasped and then successively moved up and down in the direction of arrow 30 and down with rod 19 still inserted therein, as the outlined representation in Figure 11, so that agitator disk 6a ensures thorough mixing of the liquid and powder components, while rod 19 prevents gaseous escape from tubular rod 6b due to O-ring seal 19c. The filter 21 is provided to remove heavy particulate before it can be drawn into the vacuum source 8. Once admixed, first lock 7, and then rod 19 are removed and then bottom 4 is axially displaced within cylinder 3 in a fashion similar to a piston, as previously described, so that the mixed bone cement can be pushed out of vessel 2. In this way, agitator rod 6 is pulled completely up so that agitator disk 6a contacts the top end 3b of cylinder 3, with tubular rod 6b acting as a discharge nozzle for the now-ready cement.

Figure 12 shows a fifth embodiment of the present invention wherein the mixing vessel is again pre-filled with powder component B and where container 9 has top end 9a connected to a tube 26, shown as being inserted into hole 27 which penetrates cylinder wall 3a. It is to be understood that prior to insertion of tube 26, plug 121 is inserted within hole 27, thereby maintaining a seal from the atmosphere. When introduction of liquid A is to take place, plug 121 is removed and then the tube is inserted

into hole 27. The glass ampoule containing liquid A is broken and then by percolation of air and liquid A through powder component B in mixing vessel 2, a pre-mixing is obtained. When the ampoule is emptied, tube 26 is removed from hole 27, and plug 121 is reinserted and final mixing, by means of the agitator, is performed as previously described in connection with Figure 4. After thorough mixing, lock 7 is removed, and the contents pushed upwards with piston head 80 for eventual discharge out tube 6b.

Figure 13 shows a sixth embodiment, where container 9 is now comprised of a collapsible plastic bag. This substitution advantageously reduces the cost to manufacture, and is less bothersome than breaking and discarding the glass ampoule bottles. Again, this arrangement functionally mixes the elements together as previously explained. However, as seen in Figure 13, a U-shaped sleeve member 29 is used as a valve, where tube 26 is folded and frictionally inserted within sleeve interior 29a, thereby blocking any flow of material A. Then, plug 121 is removed from cylinder wall 3a, and is inserted into hole 27. Figure 13 shows a coupling 30 being inserted into tube 26 to facilitate the connection into the cylinder wall and to allow discharge of fluid A more centrally within mixing vessel 2 once inserted through hole 27. It should be realized that the embodiments of Figures 6-12 could also be provided with coupling 30 if desired. Mixing is completed by upwardly and downwardly moving agitator disk 6a as previously described, using mouth 6c of rod 6b as a discharge nozzle once disk 6a is contacted against top end 3a of cylinder 3, and tightening rod 19 is removed so that the mixed contents can be pushed upwards by bottom 4.

Figure 14 shows a seventh embodiment of the present invention where it is seen that the means for introducing the fluid into the mixing vessel is now in the form of the same collapsible bag as that of Figure 13, but now directly inserted into tubular agitator 6B once tightening rod 19 is removed, as is shown. Then, the U-shaped sleeve member 29 is removed from tube 26 so that fluid component A is drawn under vacuum down to the bottom of tubular agitator rod 6B, and mixed as previously described. An air-tight adaptor means 42 is provided at the tube end so as to securely hold it within tube 26 during introduction of fluid A.

Figure 15 shows an eighth embodiment of the present invention where it is seen that the cylindrical containers 9 and 10 are eliminated so that once the glass ampoule 11 is broken, the liquid bone cement component A, is communicated into mixing vessel

2 via removable funnel member 50 and hollow agitator rod 6B. As seen, open funnel neck 52 is in frictional engagement with the open mouth 6B' of rod 6B when funnel 50 is inserted therein. The tip 11a of ampoule 11 is broken off and contents A are fed into funnel component receiving area 50a before descending down tube 6b. Again, this arrangement provides the liquid component at the container bottom so that both components can be pre-mixed together through percolation as previously explained. However, since there may be no longer an enclosure for sealing the ampoule once it is broken, in order to prevent atmospheric releases prior to mixing, the suction pressure on vacuum source 8 may be increased over that of the previous embodiments. High velocity ambient air entering the funnel will prevent fumes from escaping mixing vessel 2 into the surrounding environment. As a further means to prevent atmospheric escape, it is envisioned that funnel member 50 be provided with an O-ring or similar seal 54 about its open neck 52, and a cover 56 which contains an enlarged hole 51 for directing the liquid contents therethrough. In this way, the potential for fumes to escape between the rod 6B and funnel 50 are reduced by provision of cover 56, since they would be confined within the space between the cover and the funnel proper.

Figures 16 and 16A show a final embodiment of the present invention, where it is seen that the container 9 and cap 18 as presented in Figures 9 and 10, is provided in Figure 16 in a slightly modified fashion, where the glass ampoule 11 is now resting on breaking means 13 and that filter 14 is disposed below the breaking means. Furthermore, the container 9 is formed with a neck 9C that either inserts inside tubular rod 6b (similar to that of Figure 4) or as shown here, is formed so that rod 6b inserts inside neck 9C. In either case, once the connection is made, the neck and the tube are joined together by known methods of friction spin-melting the like elastomeric components together, or they can be joined by conventional methods such as gluing, threading, or snap-fitting the pieces air-tight to each other. Once connected, the cap 18 gripping means 18h are operatively threaded downward along container threads 12a, until shoulders 18s cause the glass ampoule to be broken against pointed cone 13b of the breaking means. As Figure 16A illustrates, once the ampoule 11 is broken, plug 18p is removed from cap 18 so that ambient air can be drawn into container 9 through action of suction device 8. Breaking of ampoule 11 will cause an air passage channel to form between shoulders 18s and ampoule, due to the ampoule slightly dropping after it is broken. Of course, part of

the annular shoulders 18s could be provided with one of several relieved areas (dashed lines) to ensure that an air passage is provided. As explained earlier, the in-rush of ambient air will prevent fumes from escaping to the outside during the mixing process.

The liquid component A passes from container 9, downwardly through filter 14, now
5 located in neck 9c, then into hollow tubular member 6b, before passing through a second filter 14b at tube open end 6e. The liquid A then changes direction at the bottom of mixing vessel 2 due to the action of vacuum source 8 and turns upwardly to percolate into the powdered bone cement component B. Plug 18p is then re-inserted into opening 18d

to seal container 9 from the atmosphere after contents A are emptied. The container 9 is
10 then gripped as a handle and stroked up and down, thereby causing agitator disk 6a to mix the two bone cement components together, as previously explained with the other

embodiments. As Figure 16 shows, tubular element 6b is scored with an annular notch 6s, that allows the container-tubular rod to be separated from each other by snapping the container in a perpendicular direction to the rod, thereby breaking the rod at the notch.

This step is performed after mixing is complete and after the tubular rod and agitator stick
15 have been pulled back towards piston 80. Once the tubular element 6b is pulled back, mixing vessel 2 is turned upside down in order to facilitate removal of the mixed bone cement. A comparison of Figure 16 to Figure 9 makes this point more clear in that

mixing vessel 2 in Figure 16 is initially upside down such that spout 5 is sealed with a
20 removable closure 5a and where the cylindrical container outer wall 3a also acts as the mixing vessel bottom, wherein the agitator 6 is inserted through the bottom of the container 3, rather than through the spout 5, as with the previous embodiments. With this

arrangement, once the mixing is completed and the rod fractured at notch 6s, pin 7 is removed, as is vacuum source 8, so that piston 80 is advanced into contact with the bone

25 cement mixture in the same manner as previously described with the other embodiments, and the mixture is pushed out of mixing vessel 2 through spout 5, of course once closure 5a is unthreaded and removed. A filter 14c rests against piston 80, thereby preventing

cement from entering into the vacuum source and from escaping through the piston once it is advanced into contact with the cement. Spout 5 is used for attachment of various

30 extrusion nozzles (not shown).